

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC,)	Civil Action No.: 05-349-GMS
Plaintiffs,)	<u>Jury Trial Demanded</u>
v.)	PUBLIC VERSION
BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION,)	
Defendants.)	
<hr/>		
BAXTER HEALTHCARE CORPORATION,)	
Counterclaimant,)	
v.)	
TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC,)	
Counterdefendants.)	

**DEFENDANTS' REPLY TO
PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF**

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TABLE OF CONTENTS

	<u>Page</u>
I. Introduction.....	1
II. Baxter's Proposed Claim Constructions Are Correct	1
A. Plaintiffs' Proposed Construction Of "Any Virus Activity" Only Leads To More Ambiguity.....	2
B. Plaintiffs' Proposed Construction Of "Under Conditions Sufficient To Substantially Reduce Any Virus Activity And Resulting In An Increased Level Of Anticomplement Activity" Would Invalidate Claim 1	3
1. "Increased Level Of Anticomplement Activity" Must Mean "Increased to an Unacceptable Level"	8
2. Plaintiffs' Proposed Construction Of "Anticomplement Activity" Is Indefinite Unless The Specific ACA Assay Is Identified	12
C. Plaintiffs' Proposed Construction Of "Then Incubating The Solution Of Step (a)" Ignores The Clear Language Of Claim 1	13
D. Plaintiffs' Proposed Construction Of "Increased Anticomplement Activity Of The Solution" Simply Makes "Solution" Vague And Indefinite.....	16
E. Plaintiffs Offer No Standard By Which "Acceptable Level Suitable For Intravenous Administration" Can Be Determined	17
F. Plaintiffs Did Not Construe "About 60 CH ₅₀ units/mL," Thereby Conceding Baxter's Proposed Construction Is Proper.....	19
III. Conclusion.....	20

TABLE OF AUTHORITIES

	<u>Page</u>
Cases	
<i>Comark Commc'n, Inc. v. Harris Corp.</i> , 156 F.3d 1182 (Fed. Cir. 1998).....	7
<i>Ekchian v. Home Depot, Inc.</i> , 104 F.3d 1299 (Fed. Cir. 1997).....	11
<i>Honeywell Intern'l., Inc. v. ITT Industries</i> , 452 F.3d 1312 (Fed. Cir. 2006).....	4, 6
<i>Kraft Foods, Inc. v. Intn'l. Trading Co.</i> , 203 F.3d 1362 (Fed. Cir. 2000).....	7
<i>Leibel-Flarsheim Co. v. Medrad, Inc.</i> 358 F.3d 898 (Fed. Cir. 2004).....	8
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967, 978 (Fed. Cir. 1998) <i>aff'd</i> 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed. 2d 577 (1996)	4
<i>Multiform Desiccants Inc. v. Medzam, Ltd.</i> , 133 F.3d 1473 (Fed. Cir. 1998).....	8
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (<i>en banc</i>)	1, 4, 6, 7, 8
<i>Rheox, Inc. v. Entact, Inc.</i> , 276 F.3d 1319 (Fed. Cir. 2002).....	11
<i>Seachange Intern'l., Inc. v. C-COR, Inc.</i> , 413 F.3d 1361 (Fed. Cir. 2005).....	11
<i>Southwall Tech., Inc. v. Cardinal IG Co.</i> , 54 F.3d 1570 (Fed. Cir. 1995).....	11
<i>Unique Concepts, Inc. v. Brown</i> , 939 F.2d 1558 (Fed. Cir. 1991).....	11

I. Introduction

Apparently realizing they have little, if any, support for their proposed constructions, Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (collectively “Plaintiffs”) devote the vast majority of their Opening Claim Construction Brief (“Plaintiffs’ Opening Brief”) to attacking the considerable intrinsic evidence that supports the constructions proposed by Defendants Baxter International Inc. and Baxter Healthcare Corporation (collectively, “Baxter”). Though the claim construction methodology of *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-16 (Fed. Cir. 2005) (*en banc*) is quite clear, Plaintiffs rarely follow it. Rather than identify intrinsic evidence that supports their proposed claim constructions, Plaintiffs in most instances submit nothing more than unpersuasive attorney argument. Viewed in the context of the claim language, the specification and the prosecution history (as mandated by *Phillips*), the proper interpretations of the disputed claim terms which are capable of construction are those proposed by Baxter.

II. Baxter’s Proposed Claim Constructions Are Correct

Claim 1 of the ‘191 patent, with the disputed claim terms italicized, reads as follows:

1. A method of treating a solution of antibodies which may have virus activity, the method comprising
 - a) contacting the solution with a trialkylphosphate and a detergent *under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity*; and
 - b) *then incubating the solution of step a)* under conditions of controlled time, pH, temperature, and ionic strength, such that the *increased anticomplement activity of the solution* is reduced to an *acceptable level suitable for intravenous administration*.

A. Plaintiffs' Proposed Construction Of "Any Virus Activity" Only Leads To More Ambiguity

Plaintiffs' argument that "any" means "some" is illogical at best. In context, Plaintiffs seem to imply that "any virus activity" should be read to require only that some portion of the viruses in a solution would be "substantially reduced," but that other viruses could remain unaffected. Yet, if there were a patented method to "substantially reduce any poison" in our water supply, one would hope the effectiveness of the method would not depend upon which particular poisons are in the water. To be useful, all possible poisons would have to be substantially reduced. And, for a method that purportedly "substantially removes any virus activity" from a product that is to be intravenously administered into a patient, one also would expect the method to substantially remove "all virus activity."

In this context, to argue (as Plaintiffs do) that "any" means "some" makes no sense. If "any" means less than "all," then Plaintiffs must mean that the activity of, for example, one out of forty viruses present in a solution could be substantially reduced, but the activity of the remaining thirty-nine viruses could remain. Such a product certainly would not be safe for intravenous administration (the ultimate goal of Claim 1), yet Plaintiffs' proposed construction embraces this outcome.

Baxter's proposed construction (that "any" means "all" in the context of this claim) is more appropriate. Baxter does not contend that "all virus activity" must be inactivated, as Plaintiffs suggest. Rather, Baxter contends that the "activity of all viruses in solution" must be substantially reduced by the solvent/detergent treatment conditions of step (a). If there is no virus activity in the solution at all, no activity needs to be substantially reduced (and step (a) of Claim 1 would be unnecessary). But if there is any

virus activity in the solution, no matter what kind or type of virus, the solvent/detergent treatment must be able to substantially reduce that activity (that is, the activity of all types of viruses present in the solution). Any other construction would render the solvent/detergent treatment of step (a) pointless.

The intrinsic evidence that Plaintiffs identify supports Baxter's proposed construction, not Plaintiffs' construction. For example, Plaintiffs rely upon the Neurath reference (cited in the '191 patent) for the statement, "this invention relates to the inactivation of viruses, especially lipid enveloped viruses, e.g., hepatitis B." Plaintiffs' Opening Brief, p. 12. This statement confirms that "viruses" is a broad term – it encompasses at least lipid enveloped viruses, but also other types of viruses (such as non-lipid enveloped viruses). Further, this shows that Neurath knew how to specifically identify lipid enveloped viruses when intending to limit a discussion to only a specific type of virus. William Alonso, the named inventor of the '191 patent, also knew how to specifically identify lipid enveloped viruses. *See* Rogaski Decl., Ex. 2, Claims 21 and 23. Accordingly, when the named inventor did not so limit the term "virus," such as in Claim 1, the only logical conclusion is that "virus," and "virus activity," includes all types of viruses. Consequently, the proper construction of "any virus activity" is "activity of all viruses in solution."

B. Plaintiffs' Proposed Construction Of "Under Conditions Sufficient To Substantially Reduce Any Virus Activity And Resulting In An Increased Level Of Anticomplement Activity" Would Invalidate Claim 1

Plaintiffs are caught between a rock and a hard place when construing this term. Either their proposed construction for "under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity" is

adopted, in which case Claim 1 should be found invalid as the full breadth of the claim would not be enabled, or the proper construction proposed by Baxter should be adopted. The only “conditions” disclosed in the patent that consistently “result in an increased level of anticomplement activity” are those identified by Baxter’s proposed construction. Accordingly, this claim term should be construed consistently with the specification as “adding TNBP and cholate in an amount known to the artisan to reduce viral activity, at a pH of about 7.0 for a time known to the artisan to reduce virus activity.”

Plaintiffs contend Baxter’s construction improperly imports preferred embodiments into the claim. That argument is wrong, for at least two reasons. First, Plaintiffs confuse improperly importing limitations with properly construing claims through the eyes of the skilled artisan using the specification as “a guide to the meaning of the disputed term.” *Phillips*, 415 F.3d at 1315 (“[C]laims ‘must be read in view of the specification, of which they are a part.’ *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1998), *aff’d* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed. 2d 577 (1996). ‘Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’”). If the claim language, in light of the specification and file history, makes it clear that a skilled artisan would have understood the claims to require a particular construction, then that is how the claim term should be construed. *See Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006), *citing Phillips*, 425 F.3d at 1315 (holding “fuel filter is the only ‘fuel injection system component’ that the claims cover, and that a fuel filter was not merely discussed as a preferred embodiment.”). Second, the embodiments that Plaintiffs contend Baxter is importing are not merely preferred embodiments but, instead, are the only conditions actually disclosed by the specification

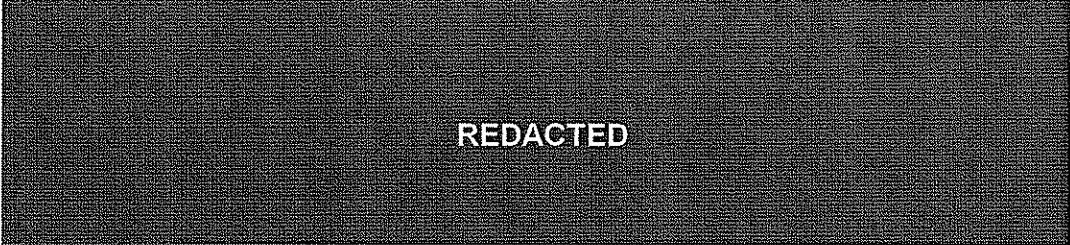
that are encompassed by Claim 1.

The context of this term within Claim 1 makes clear that the “conditions . . .” must increase the anticomplement activity (“ACA”) level of the solution. This requires: (1) particular conditions that substantially reduce virus activity and increase ACA; and (2) that the ACA level of the solution actually increases to an unacceptable¹ level as a result of the conditions. Since the claim term “under conditions . . . resulting in an increased level of anticomplement activity” does not expressly recite the required “conditions,” the Court must go further than just the claim language and also consider the specification and file history to determine which conditions increase, as opposed to decrease, ACA levels.

As shown in Baxter’s Opening Claim Construction Brief (“Baxter’s Opening Brief”), with the exception of two outlier values, solvent/detergent treatment at pH 5.8 results in acceptable ACA levels after the solvent/detergent treatment, while treatment at pH 7.0 – without exception – results in unacceptable ACA levels. Baxter’s Opening Brief, Section V1.B.2. Consequently, a skilled artisan reading the specification would readily understand that the “conditions” of step (a) include pH 7.0 and exclude pH 5.8.

Similarly, there is only one data point in the patent regarding treatment with TNBP/Tween. All other data points are with TNBP/cholate. Baxter’s Opening Brief, Section V1.B.1. A skilled artisan would not rely on a single data point to reach a conclusion, so would not reasonably interpret the data in the ‘191 patent for treatment with TNBP/Tween as resulting in unacceptable ACA levels. REDACTED

¹ As discussed in Section II.B.1, *infra*, proper interpretation of the term “an increased level of anticomplement activity” means ACA increased to a level unacceptable for intravenous administration.



REDACTED

In contrast, every data point in the patent for which the solution was treated with TNBP/cholate at pH 7.0 resulted in unacceptable ACA levels. Consequently, a skilled artisan reading the specification would reach the inescapable conclusion that solvent/detergent treatment with TNBP/cholate at pH 7.0 are the “conditions” that result in ACA being increased to an unacceptable level. These are the only such “conditions” that flow from the specification. Thus, Baxter’s proposed construction flows properly from the application of the *Phillips* methodology – consulting the specification (“the single best guide to the meaning of a disputed term”) to understand the proper scope and interpretation of the claims.

Construing this claim term to be limited to treatment with TNBP/cholate at pH 7.0 does not improperly import preferred embodiments into the claim. Nowhere in the specification are the conditions of TNBP/cholate treatment at pH 7.0 described as being preferred. These conditions are simply the only ones that consistently resulted in an increase of anticomplement activity to a level unacceptable for intravenous administration. *See Honeywell*, 452 F.3d at 1318, *citing Phillips*, 425 F.3d at 1315 (holding “a fuel filter is the only ‘fuel injection system component’ that the claims cover, and that a fuel filter was not merely discussed as a preferred embodiment.”). Just as in the *Honeywell* case, here solvent/detergent treatment with TNBP/cholate at pH 7.0 are the only disclosed conditions that Claim 1 covers – they are not merely a preferred

embodiment.

Plaintiffs also argue that Baxter's construction excludes embodiments. In so doing, Plaintiffs admit that "material incubated at pH 5.8 had lower ACA levels than the pH 7.0 samples," but argue from this that limiting Claim 1 to pH 7.0 "would exclude the very embodiments of the invention that the specification teaches produce the best results." Plaintiffs' Opening Brief, p. 15. Baxter agrees that better conditions for obtaining an intravenously administrable solution would be to treat the solution at pH 5.8 rather than at pH 7.0 (because treatment at pH 5.8 generally does not increase ACA to unacceptable levels). But, neither the best conditions nor even better conditions are what is claimed in Claim 1. Claim 1 reflects the "surprising result" of an increase of ACA following solvent/detergent treatment. Treatment at pH 5.8 avoids such an increase, so would not fall within Claim 1. Accordingly, limiting Claim 1 to pH 7.0 does not exclude a preferred embodiment as Plaintiffs contend. It simply includes the only conditions described in the specification that consistently result in the claimed increased ACA levels after solvent/detergent treatment. To construe Claim 1 more broadly would be to impermissibly broaden the proper reach of the claim such that the full scope of the claim would not be enabled (for example for treatment at pH 5.8).

Plaintiffs also invoke the claim differentiation doctrine. But, while claim differentiation is a policy, it is not "a hard and fast rule," and cannot prevent the proper application of the *Phillips* claim construction methodology, discussed above. *Kraft Foods, Inc. v. Int'l. Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000), *citing Comark Commc'n, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). Moreover, "claim differentiation can not broaden claims beyond their correct scope." *Kraft Foods*, 203

F.3d at 1368, *citing Multiform Desiccants Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998). The presumption that an additional limitation in a dependent claim is not found in the independent claim from which it depends can be overcome “if the evidence favoring a different claim construction is strong.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910-11 (Fed. Cir. 2004). Here, the evidence favoring Baxter’s construction of this claim is strong and, thus, should overcome the presumption of claim differentiation. As discussed above, the specification makes abundantly clear that “under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity” is properly construed to mean “adding TNBP and cholate in an amount known to the artisan to reduce viral activity, at a pH of about 7.0 for a time known to the artisan to reduce virus activity.”

1. “Increased Level Of Anticomplement Activity” Must Mean “Increased to an Unacceptable Level”

The intrinsic evidence unequivocally establishes that the “increase” in ACA after solvent/detergent treatment must be to an “unacceptable” level. If claim terms were construed in a vacuum, without regard to even the context of the claim in which the terms appear, Plaintiffs might be correct that “increased anticomplement activity” “requires no construction.” But, as *Phillips* requires, claim terms are construed in the context of the claim itself, with additional consideration of the specification and prosecution history. When this intrinsic evidence is ignored, as Plaintiffs attempt to do, this claim term becomes divorced from the clear meaning attributed to it by the applicant. When this intrinsic evidence is properly consulted, the correct meaning becomes apparent.²

² Plaintiffs argue Baxter’s construction “is inconsistent with the claim language itself, the specification, and the prosecution history,” but offer no explanation to support this bald

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The plain language of Claim 1 itself requires that the ACA level after solvent/detergent treatment (step (a)) be “unacceptable.” If the ACA level after step (a) was not unacceptable, it would be nonsensical to have an incubation step (step (b)) to reduce ACA “to a level acceptable for intravenous administration.” Rogaski Decl., Ex. 2, Claim 1 (emphases added). If the ACA already is acceptable, it cannot be reduced “to a level acceptable ...!”

Moreover, the specification confirms that the incubation step (step (b)) reduces “the anticomplement activity (ACA) resulting from viral inactivation treatment of a solution of antibodies ... to an acceptable level.” See Rogaski Decl., Ex. 2, Abstract (emphases added). Confirming that the ACA level before incubation must be unacceptable, the applicant *expressly stated* that the solvent/detergent treatment of step (a) “results in a product with an acceptable viral inactivation but with unacceptably high levels of ACA.” Rogaski Decl., Ex. 2, Col. 2:6-10 (emphasis added). And, because unacceptable levels purportedly result from solvent/detergent treatment, the applicant represented, “the incubation step [*i.e.*, step (b) of claim 1] is necessary to achieve an acceptable level of ACA low enough to allow the [immunoglobulins] to be administered by intravenous injection.” Rogaski Decl., Ex. 2, Col. 2:31-34 (emphasis added). That is, without the incubation step following the solvent/detergent treatment, the ACA level would be unacceptable. Or, once more, the incubation step (step (b)) is required because

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assertion. Indeed, they identify no inconsistencies whatsoever. As the intrinsic evidence identified in Baxter’s Opening Brief and reply brief shows, Baxter’s construction has considerable support. Moreover, Baxter’s construction is also supported by the citations to the intrinsic evidence in Plaintiffs’ Opening Brief at footnote 3.

the ACA after the solvent/detergent treatment (step (a)) is unacceptably high. As the applicant argued in its opening appeal brief to the Patent Board of Appeals, “[i]f there is no such increase, then step (b) of the invention, and *the invention itself*, is not needed.” See Docket No. 161, Joint Appendix (“JA”) 98 (emphasis added).

The construction proposed by Baxter was utilized by the Board of Patent Appeals, which stated in its Decision on Appeal, “the claimed subject matter requires that the inactivation step result in an increase in ACA levels, and a reduction in that claimed increase by the incubation step *to a point where the solution is suitable for intravenous use.*” Id. at JA 125 (emphasis by bold/italics added; emphasis by underlining in original). Again, if the ACA has to be reduced by incubation to reach a point where the solution is suitable (or “acceptable”) for intravenous administration, it must have been unsuitable (or “unacceptable”) for intravenous administration before incubation.

Faced with such unequivocal statements in the patent and during prosecution, Plaintiffs resort to meritless half-hearted arguments. For example, Plaintiffs confusingly argue that, because the specification mentions it would be desirable to have ACA levels as low as possible, it would be inconsistent for the ACA levels after solvent/detergent treatment to be “unacceptable.” Plaintiffs, however, seemingly ignore the fact that, according to Claim 1, it is only the ACA levels in the final solution (i.e., after the incubation step, not after solvent/detergent treatment) that must be acceptable. They also ignore the requirement that the incubation step reduce ACA levels to acceptable levels. That the final solution must have acceptable ACA does not require acceptable ACA levels prior to incubation; indeed, that would contravene the express purpose of the incubation step – to reduce ACA to acceptable levels.

Plaintiffs also surprisingly argue that statements made by the applicant during prosecution of the claims at issue simply “were illustratively used in discussions regarding whether combining the prior art would have been obvious to Dr. Alonso. They were not used to limit the claims.”³ Plaintiffs’ Opening Brief, p. 18. Statements made to avoid prior art, however, are absolutely relevant to the meaning of claim terms and do limit claims. “Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.” *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995), *citing Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991). “Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language.” *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005), *citing Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1325 (Fed. Cir. 2002) (“Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations . . .”); *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997) (“[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection.”). The applicant of the ‘191 patent is bound by the representations it made to the Patent Office. The public must be able to rely on such public information to determine the metes and bounds of the “invention.” *Seachange*, 413 F.3d at 1372.

Plaintiffs also argue that Baxter’s construction is contrary to specific data points

³ Tellingly, Plaintiffs do not identify any particular statements in the prosecution history that were mere “illustrations.”

in the patent. But the claims in the '191 patent were not obtained based on specific data points. Rather, they were obtained based on averages of data points (including obvious outlier values that significantly increased the average) in the '191 patent. The Figure in the '191 patent, expressly relied upon by the applicant during prosecution, clearly shows the average ACA level after solvent/detergent treatment (for samples A1-A4) have unacceptable ACA (60 CH₅₀ units, where the acceptable level is 45 CH₅₀ units.) *See* Rogaski Decl., Ex. 2, Figure; and Docket No. 161, JA99 ("In the enclosed revised Figure (submitted earlier only to help understand the invention and not for purposes of being a Formal Drawing), the increased ACA observed [to the averaged 60CH₅₀ units] when using the viral inactivation technique of Neurath et al. (see middle bar) was surprising."). Had Plaintiffs relied on the specific data points during prosecution (or excluded the outlier A4 value, without which the average would not have been unacceptable), the "invention" likely would not have been patented because much of the data in the patent does not support the "invention." But any inconsistencies between the specific data points in the specification and the claim language is an invalidity issue, not a claim construction issue. The clear statements made by the applicant during prosecution and applicant's reliance on the averaged values in the Figure confirm that "increased level of anticomplement activity" should be construed as "increased anticomplement activity of the solution from a level acceptable for intravenous administration to a level unacceptable for intravenous administration."

2. Plaintiffs' Proposed Construction Of "Anticomplement Activity" Is Indefinite Unless The Specific ACA Assay Is Identified

Plaintiffs contend that Baxter's proposed construction improperly focuses on the unit of measurement of ACA rather than the definition of ACA. While Baxter agrees that

providing the particular unit used to quantify ACA is quite specific, Plaintiffs' proposed construction is on the other end of the spectrum - it provides too little meaning.

Plaintiffs' proposed construction, "the ability of antibodies to bind complement," though included in the specification, is meaningless because all antibodies theoretically have the ability to bind complement. To give this term meaning, the measured capability of proteins to bind or activate complement must be a part of the definition. And, to measure the binding capability, the assay used also must be identified.

As discussed in Baxter's Opening Brief, ACA assays must be validated for particular products. Baxter's Opening Brief, Section II.D. Because of this, they give results that cannot be correlated to other assays not validated for that product. Rogaski Decl., Ex. 23. Consequently, any definition of "anticomplement activity" in this type of claim must identify the particular assay used to measure ACA (*i.e.*, the ACA assay validated for that particular product). Without identification of the particular assay used to measure ACA, the actual ACA of the solution is not properly defined. It is not enough simply refer to the theoretical ACA of a solution (the theoretic ability of antibodies in the solution to bind complement), as does Plaintiffs' proposed construction. Accordingly, the proper construction of "anticomplement activity" is "the amount of protein capable of activating complement in an optimally titered complement and red blood cell/hemolysin system, as determined by the particular anticomplement activity assay used to obtain the anticomplement activity data reported in the '191 patent."

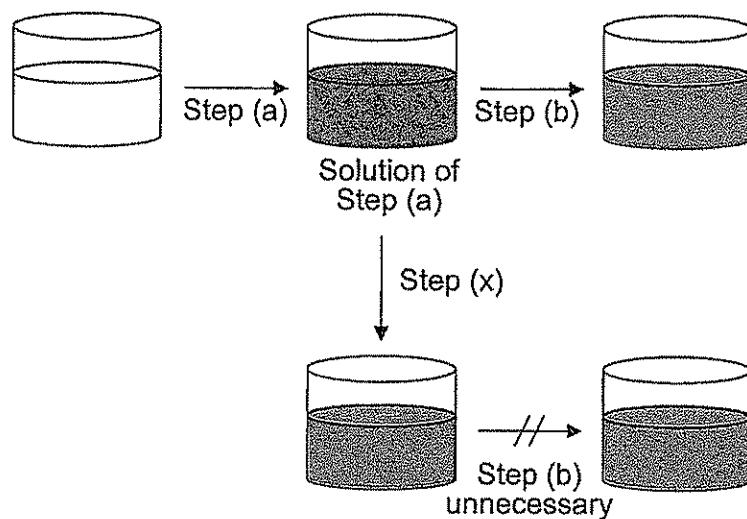
C. Plaintiffs' Proposed Construction Of "Then Incubating The Solution Of Step (a)" Ignores The Clear Language Of Claim 1

Plaintiffs argue that the phrase "incubating the solution of step (a)" is "clear on its face," and then proceed to add a dozen words to it that would entirely change its

meaning. The “solution of step (a)” is plain and simply the “solution of step (a)”; no more, no less.

While the word “comprising” in the preamble usually would make a claim “open,” here the language of Claim 1 very specifically requires that the “solution of step (a)” -- not any solution resulting from other processing steps -- be incubated. There is only one “solution of step a) – the solution resulting from the solvent/detergent treatment of step (a).

In the illustration below, the “solution of step (a)” is shown by the blue solution in the container. Incubating that solution is precisely what is contemplated by Claim 1. If, however, an additional step (step (x)) is added between the solvent/detergent treatment (step (a)) and incubation (step (b)), the resulting solution (the green solution in the container) is no longer “the solution of step (a).” The solution has been changed by that further processing step. And, step (x) may entirely obviate the need for the incubation step (step (b)), for example, if it lowers ACA to an already acceptable level.



Because Claim 1 specifically identifies the solution to be incubated ("the solution of step (a)'), additional steps are not permitted between steps (a) and (b).

That additional steps cannot be carried out between steps (a) and (b) does not, however, preclude a solution from being rendered intravenously administrable as Plaintiffs would have the Court believe. Nothing in the claim prevents solvent/detergent removal steps or tonicity adjustment steps from being performed after the incubation step (step (b)). Plaintiffs argue that, because in one preferred embodiment, removal of solvent/detergent was carried out after solvent/detergent treatment, this claim term should be interpreted to permit such a step between step (a) and step (b). Such an argument violates the policy relied upon so heavily by Plaintiffs in their Opening Brief against importing limitations from the specification into the claim. Moreover, while removal of solvent/detergent prior to incubation is consistent with the language of Plaintiffs' European claims, it is inconsistent with the plain language of Claim 1 in the '191 patent. The European claims expressly allow for (and, in fact, require) removal of solvent/detergent before incubation; in contrast, the U.S. claims do not allow for any such step between steps (a) and (b) as the clear language requires incubation of the "solution of step (a)." Rogaski Decl., Ex. 27. Accordingly, any such additional processing steps must occur after incubation for such a solution to fall within Claim 1.

In view of the plain language of Claim 1 and the supporting intrinsic evidence, "then incubating the solution of step (a)" should be construed to mean "incubating the solvent/detergent treated solution resulting from step (a) without any additional processing steps between steps (a) and (b)."

D. Plaintiffs' Proposed Construction Of "Increased Anticomplement Activity Of The Solution" Simply Makes "Solution" Vague And Indefinite

Plaintiffs argue that the phrase "increased anticomplement activity of the solution" needs no construction, but that it means "an increase in the ACA levels of a solution as a result of contacting the solution with a solvent and detergent." Plaintiffs' Opening Brief, p. 23. Baxter agrees that the increased ACA referred to in step (b) of Claim 1 must refer to the increased ACA in the solution resulting from the solvent/detergent treatment step (step (a)) for this claim term to make sense. There is no dispute that the solvent/detergent treatment step must increase the ACA level of the solution to some level and that the incubation step must then decrease that increased ACA. If there are no processing steps between step (a) and step (b), clearly "the solution" is the solution resulting from step (a).

But Plaintiffs argue that other processing steps can be included between step (a) and step (b). If additional steps between step (a) and step (b) were permitted, and those steps reduced ACA after step (a), the incubation step (step (b)) would be rendered superfluous. See Figure, above. And, if such an additional processing step is used after step (a), the solution to be incubated would no longer have the "increased anticomplement activity" that resulted from step (a). It would be a different ACA level – lower than that resulting from step (a) and possibly already acceptable (in which case the incubation step would be entirely unnecessary). Plaintiffs' proposed construction, therefore, makes this claim term indefinite.

Accordingly, if the inclusion of "solution" does not render this claim term indefinite, the proper construction of "increased anticomplement activity of the solution" is "increased anticomplement activity of the solution of step (a)."

E. Plaintiffs Offer No Standard By Which “Acceptable Level Suitable For Intravenous Administration” Can Be Determined

Plaintiffs’ Opening Brief misses the point regarding the proper construction of “acceptable level suitable for intravenous administration.” Plaintiffs focus on the fact that “[a] person of ordinary skill in the art would know that when intravenously injecting immune serum globulins into a patient, ACA has to be at an acceptable level.” Plaintiffs’ Opening Brief, p. 24. Of course. But, this begs the question, “what level is

“acceptable?”

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Plaintiffs are misguided in their attempt to inject the limitation “as low as possible” into the claim. The claim language nowhere contains the words “as low as possible.” It only uses the term “acceptable.” Moreover, Plaintiffs expressly defined this term during prosecution, but that definition did not include the “as low as possible” language. *See*, Docket No. 161, JA83; Rogaski Decl., Ex. 2, Col. 5:57-64. Such language would, in any event, not lend meaning to this term. A skilled artisan can always try to reduce the ACA level of a solution to that which is “as low as possible,” but if that level is not also “acceptable,” the solution will not fall within Claim 1 of the ‘191 patent.⁴ Adding the phrase “as low as possible” only makes this term more indefinite.

⁴ Plaintiffs provide the analogy of meeting acceptable levels for pollution. Plaintiffs’ Opening Brief, p. 25. Yet, this analogy also supports Baxter’s proposed construction. Before a company could be fined for not meeting acceptable pollution levels, the company must know what the acceptable level is. That company may still aim to reduce pollution levels even further (even as low as possible), but a numeric value against which to compare is absolutely necessary for a company to know whether its levels are below the limit.

To give this term meaning, some standard for acceptability must be provided so a person of ordinary skill can determine whether or not a solution falls within the scope of Claim 1. Plaintiffs appear to rely on the fact that regulatory agencies set a general standard for ACA acceptability. While this may be true in Europe, it is not true in the United States. The U.S. Food and Drug Administration (“FDA”) has not set a universal limit for acceptable ACA levels; rather, it approves particular products and sets particular limits for the ACA levels on a per-product basis. And, the particular limits set by the FDA for specific products are not generally known to a person of ordinary skill in the art, so that cannot inform the artisan’s understanding of “acceptable.” Certainly, Dr. Alonso did not know them! Moreover, the particular ACA levels for a product are obtained using ACA assays validated for the particular product, which also are not generally known to a skilled artisan.⁵ Thus, release limits set by the FDA for specific products cannot help define this term.

The measure of whether an ACA level is “acceptable” must be defined in view of the intrinsic evidence. During prosecution of the ‘191 patent, the Patent Office withdrew an objection that “acceptable level” was vague and indefinite based on the applicant’s “definition of an acceptable level found in the specification at page 9 [of the application as filed, and Col. 5:57-64 of the 191 patent].” Docket No. 161, JA83. There, the applicant represented that for a 5% solution, an “acceptable level” was “less than about

⁵ Plaintiffs admit that there are “multiple methods for measuring ACA.” But, Plaintiffs ignore their own publication showing that different methods for measuring ACA result in different values that cannot be correlated. Rogaski Decl., Ex. 23. That a skilled artisan may know of a certain method for measuring ACA does not allow that skilled artisan to determine whether the obtained result is “acceptable” as that word is used in Claim 1 of the ‘191 patent.

45 CH₅₀ units/mL,” and for a 10% solution, an “acceptable level” was “less than about 60 CH₅₀ units/mL.” Though Baxter believes “acceptable level” is still vague and indefinite, Plaintiffs cannot contend that “acceptable level” is defined by something other than the discussion at Col. 5:57-64. Contrary to Plaintiffs’ protestations, using the applicant’s definition of “acceptable level” does not constitute importing preferred embodiments into the claim – it constitutes properly construing this claim term. There is no other guidance in the intrinsic evidence as to what “acceptable” means.

To the extent this claim term is capable of construction at all (which Baxter disputes), it can only mean “a defined numerical level that depends upon the protein concentration, specifically, 60 CH₅₀ units/mL for a 10% solution and 45 CH₅₀ units/mL for a 5% solution, as determined by the particular anticomplement activity assay used to obtain the anticomplement activity data reported in the ‘191 patent.”

F. Plaintiffs Did Not Construe “About 60 CH₅₀ units/mL,” Thereby Conceding Baxter’s Proposed Construction Is Proper

Plaintiffs incorrectly state that “no construction of ‘about 60 CH₅₀ units’” is needed because they withdrew Claim 5. Plaintiffs have not withdrawn Claim 2⁶, in which this term also is used. Because this term is in an asserted claim and is disputed by the parties, it requires construction. As Plaintiffs offered no proposed construction of this term in their Opening Brief, Baxter’s proposed construction “about 60 CH₅₀ units/mL, as

⁶ Plaintiffs originally asserted each of Claims 2 and 5-6. Immediately before the opening claim construction briefs were due, Plaintiffs withdrew Claims 5-6. In Plaintiffs’ Supplemental Interrogatory Responses, served after the opening claim construction briefs were filed, Plaintiffs appear to no longer be asserting infringement of Claim 2, though Plaintiffs have not affirmatively so advised Baxter. It appears Plaintiffs are attempting to remove these claims from consideration to avoid a negative claim construction. Yet, this claim term requires construction, even if Plaintiffs no longer assert infringement of these claims, because Baxter has not withdrawn its allegations of invalidity of these claims.

determined by the particular anticomplement activity assay used to obtain the anticomplement activity data reported in the '191 patent" should be adopted.

I. Conclusion

When the intrinsic evidence is properly considered, Baxter's proposed constructions should be adopted, as they comport with the plain language of the claims, the specification and the prosecution history.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on November 27, 2006, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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